UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

ABBVIE INC., *et al.*, *Plaintiffs*, *v.* JONATHAN SKRMETTI, in his official capacity as ATTORNEY GENERAL OF THE STATE OF TENNESSEE *Defendant.*	Case No. 3:25-cv-00519 Judge Aleta A. Trauger

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, TENNESSEE HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

William T. Ramsey (#009245)
James G. Thomas (#007028)
Nathan C. Sanders (#033520)
Simon N. Levitsky (#040944)
NEAL & HARWELL, PLC
1201 Demonbreun St., STE 1000
Nashville, TN 37203
(T) (615) 238-3503
(F) (615) 726-0573
wtr@nealharwell.com
jthomas@nealharwell.com
nsanders@nealharwell.com
slevitsky@nealharwell.com

William B. Schultz
Margaret M. Dotzel
Ezra B. Marcus
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
emarcus@zuckerman.com

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INTEREST OF *AMICI CURIAE*

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Tennessee's legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Tennessee Hospital Association** (THA) is a not-for-profit membership association that serves as an advocate for hospitals, health systems and other healthcare organizations and the patients they serve. THA also provides education and information for its members and informs the public about hospitals and healthcare issues at the state and national levels.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice and advanced education and professional development, and has served as a steadfast advocate for members and patients.

INTRODUCTION

Over the past five years, nearly 40 drug companies, including Plaintiffs (collectively, AbbVie), have broken with decades of precedent and begun to refuse to ship drugs purchased by 340B hospitals to their contract pharmacies. The federal government believed this was unlawful and sought to require manufacturers to continue delivering these drugs to contract pharmacies on the same terms on which they delivered those drugs to 340B in-house hospital pharmacies.[1]

The drug companies fought that effort tooth and nail. In lawsuit after lawsuit, they argued that the federal government could not interfere with their contract pharmacy restrictions. The companies began with the premise that the federal 340B statute had absolutely nothing to say about delivery—*i.e.*, how and where drugs can and cannot be delivered—and insisted that their new policies were *delivery* restrictions.[2] The drug companies won. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023) (Section 340B's "text is silent about delivery").

Like many other states, Tennessee has filled the federal statutory gap that drug companies spent years fighting for by requiring shipment of 340B drugs to contract pharmacies. Faced with the drug industry's unprecedented assault on Tennessee's health care safety net and the

[1] *See, e.g.*, Letter from Dep't of Health & Hum. Servs., Health Resources & Servs. Admin. Administrator C. Johnson to AbbVie, Inc. Vice Pres., U.S. Market Access C. Compisi (Oct. 17, 2022), https://www.hrsa.gov/sites/default/files/hrsa/opa/programintegrity/hrsa-letter-abbvie-covered-entities.pdf.

[2] *E.g.*, Novartis Opening Brief at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, Doc. 1949831 (D.C. Cir. June 8, 2022) ("Section 340B . . . is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies."). AbbVie's counsel made similar arguments on behalf of another drug company. *See* Eli Lilly Opening Brief at 2–3, *Eli Lilly and Company. v. Becerra*, Nos. 21-3128 & 21-3405, Doc. 19 (7th Cir. May 25, 2022) (arguing that no part of Section 340B "says anything at all about delivery or sale to third parties besides covered entities").

acknowledged gap in federal law, the Tennessee legislature enacted Senate Bill 1414 ("S.B. 1414"). S.B. 1414's central provision does only what the pharmaceutical industry and the federal courts said the *federal* law did not do: regulate the delivery of 340B drugs. *See* S.B. 1414 § 1(c) (prohibiting drug companies from restricting "the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity or other location that is under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity").

Now comes the whiplash: AbbVie claims in its Complaint that "S.B. 1414 is a *price* regulation." Compl., ECF No. 1, ¶ 141 (emphasis added). Even though Tennessee has plainly legislated in precisely the area that drug companies successfully insisted was not addressed under federal law—the delivery of 340B drugs—AbbVie has reversed course in this litigation to claim that S.B. 1414 is preempted by federal law. And as part of that about-face, AbbVie now insists that states cannot fill the federal statutory gap that drug companies spent years fighting for.

This history is important—and not just because it situates AbbVie's claims within a broader effort by the drug industry to undermine the 340B program. It also serves as a reminder of *why* Tennessee chose to step into the federal statutory void. Put simply, Tennessee acted because drug companies and the federal courts all but invited it to.

The primary issue here is whether Tennessee, exercising its historic police power over health and safety, can fill the gap in the federal 340B statute and regulate the delivery of 340B drugs (purchased by 340B hospitals) to contract pharmacies. It can. Numerous district courts have said so,[3] as has the Eighth Circuit in the only Court of Appeals decision to date addressing a drug

[3] *See AstraZeneca Pharms. LP v. Bailey*, No. 2:24-cv-4143-MDH, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881 (W.D. Mo. Feb. 13, 2025); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507 (S.D. Miss. Dec. 23, 2024); *PhRMA v. Murrill*, No. 6:23-cv-997, 2024 WL 4361597

industry challenge to a state contract pharmacy statute. *See PhRMA v. McClain*, 95 F.4th 1136, 1143–45 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024).

At bottom, AbbVie's attack on S.B. 1414 is really an attack on federalism itself. AbbVie tries to transform an acknowledged federal statutory silence into a reason to displace "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). That is not the law, and each of AbbVie's claims seeking to undermine Tennessee's lawful exercise of traditional state authority should be rejected.

ARGUMENT

Amici curiae begin by highlighting critical flaws in AbbVie's claims under the Supremacy Clause, the Takings Clause, and the First Amendment.[4] *Amici* then address why an injunction would not serve the public interest because of the critical role of 340B hospitals in providing healthcare services to underserved communities, including through partnerships with contract pharmacies and associated 340B program savings.

I. NONE OF ABBVIE'S CLAIMS IS LIKELY TO SUCCEED.

A. AbbVie's Supremacy Clause Claim Fails.

1. AbbVie lacks a cause of action to assert federal preemption.

In its first claim for relief, AbbVie asserts a cause of action for "Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2." Compl. at 46. But such a claim fails at the outset

(W.D. La. Sept. 30, 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. July 1, 2024).

[4] *Amici curiae* do not address AbbVie's claims under the dormant Commerce Clause and the void-for-vagueness doctrine. Many courts have rejected similar challenges to state contract pharmacy statutes, *see supra* note 3, and General Skrmetti convincingly explains why this Court should reach the same result here, *see* Def.'s Resp. in Opp. to AbbVie's Mot. for Preliminary Relief ("Opp."), ECF No. 23, at 16–20.

because, as the Supreme Court has explained, the Supremacy Clause "does not create a cause of action" through which a plaintiff may claim that state law is preempted. *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 325 (2015).

AbbVie also cannot challenge S.B. 1414 as preempted through a claim in equity. *See id.* at 326–28 (discussing claims in equity as recognized in *Ex parte Young*, 209 U.S. 123 (1908)).[5] A "threshold inquiry" for such a claim is whether the federal statute gives the plaintiff "a federal right of [its] own to vindicate," *Safe Streets All. v. Hickenlooper*, 859 F.3d 865, 903 (10th Cir. 2017), which requires that the statute be "phrased in explicit rights-creating terms." *Gonzaga University v. Doe*, 536 U.S. 273, 287 (2002); *see also Murphy v. NCAA*, 584 U.S. 453, 478–79 (2018) (to support a claim for preemption, a federal statute must "confer[] on private entities . . . a federal right to engage in certain conduct subject only to certain (federal) constraints").

There is no "rights-creating" language in the 340B statute that could give rise to AbbVie's claim that S.B. 1414 is preempted. In fact, drug companies' only arguable rights under the 340B statute run against covered entities, *see* 42 U.S.C. § 256b(d)(3)(A), but even there, the statute forecloses a civil cause of action by creating an "*administrative* process" through which HRSA is charged with "reviewing and *finally resolving*" any claimed violations, *id.* § 256b(d)(3)(B)(i) (emphasis added). *See Armstrong*, 575 U.S. at 329 (noting that "the express provision of an administrative remedy" supported conclusion that statute "preclude[d] private enforcement . . . in

[5] Such a claim in equity is "quite apart from any cause of action conferred by the Supremacy Clause." *Armstrong*, 575 U.S. at 327. Here, although AbbVie cites *Ex parte Young* as an alleged basis for the Court's *jurisdiction*, *see* Compl. ¶ 32, it asserts its first claim for relief "Under the Supremacy Clause." *Id.* at 46.

the courts"). This has led the Supreme Court to note "the incompatibility of private suits with the [340B] statute." *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 114, 121 (2011).[6]

Because AbbVie has no valid cause of action through which to bring a claim that S.B. 1414 is preempted, its first claim for relief fails and should be dismissed.

2. S.B. 1414 Is not preempted.

Even if AbbVie could assert a preemption challenge, its claim would fail because S.B. 1414 is not preempted. Similar preemption challenges to contract pharmacy statutes have been rejected by numerous district courts as well as the Eighth Circuit.[7] This Court should follow suit.

a. Congress did not create or occupy a field in the 340B statute.

AbbVie first asserts a field-preemption theory, claiming that "Section 340B erects a comprehensive regulatory scheme governing an exclusively federal program," and that "every detail of the 340B program is determined by federal law." Pls.' Mot. for a Prelim. Inj. ("Mot."), ECF No. 18, at 9–10. AbbVie's field preemption theory both misapplies the relevant standard and mischaracterizes the 340B statute.

Field preemption occurs only in narrow circumstances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy*, 584 U.S. at 479 (citation omitted). Indeed, "[t]he subjects of modern social

[6] AbbVie does not argue that the 340B statute itself creates a private right of action. Nor could it: the Supreme Court has explicitly held that the statute creates no private right of action for covered entities, and the Court's rationale applies equally to manufacturers. *See Astra USA, Inc.*, 563 U.S. at 117 ("Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities.").

[7] *See PhRMA v. McClain*, 95 F.4th at 1143–45; *see also, e.g.*, *Novartis v. Fitch*, 738 F. Supp. 3d at 747; *AstraZeneca v. Fitch*, 2024 WL 5345507, at *4–9; *Novartis v. Bailey*, 2025 WL 489881, at *2–4. The only decision in which a court found a similar state contract pharmacy statute to be preempted is *PhRMA v. Morrissey*, 760 F. Supp. 3d 439 (S.D.W. Va. 2024), and *amici* respectfully submit that *Morrissey* was wrongly decided for the reasons articulated by General Skrmetti. *See* Opp. at 13–14.

and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has "reject[ed] . . . the contention that pre-emption is to be inferred merely from the comprehensive character" of a federal statute. *Id.* Rather, a statute preempts an entire field only if it "reflect[s] a congressional decision to foreclose any state regulation in the area," and thus "confer[s] a federal right to be free from any other" requirements in the same field. *Murphy*, 584 U.S. at 479 (citation omitted).

AbbVie relies entirely on the (supposed) comprehensiveness of the 340B statute to support its field preemption theory. *See* Mot. at 9–11. But nowhere does AbbVie suggest that the 340B statute evinces Congress's intent to foreclose complementary state law. *See id.* AbbVie notes that the 340B statute does not *affirmatively* "authorize[] state regulation," *id.* at 10, but that argument flips preemption analysis upside down. Congress knows that, in many areas, it legislates against a backdrop of additional state regulation, and Courts presume that Congress generally *does not* intend to preempt state law. *See Medtronic*, 518 U.S. at 485. That is especially true in "matters of health," given "the historic primacy of state regulation" in that area. *Id.* Moreover, countless aspects of a drug company's contractual relationships with purchasers are governed by ordinary contract law, which of course is traditionally the province of states. *See, e.g.*, *AbbVie Endocrine Inc. v. Takeda Pharm. Co.*, 2021 WL 4302920, at *3 (Del. Ch. Sept. 22, 2021) (adjudicating breach-of-contract dispute involving drug-sale contract under state law). Nothing in the 340B statute suggests that Congress intended to oust states from their traditional role in regulating these areas, and AbbVie thus cannot meet its "burden of overcoming th[e] presumption" against preemption. *PhRMA v. Walsh*, 538 U.S. 644, 662 (2003).

Moreover, AbbVie is simply wrong that "every detail" of drug manufacturers' sales to 340B entities is dictated by the 340B statute. Mot. at 10. In particular, as the drug indusry urged, *see supra* at 2 & n.2, courts have held that the 340B statute is "silent about delivery conditions," *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). For precisely that reason, the Eighth Circuit concluded that the 340B statute is *not* comprehensive and rejected a field preemption challenge to a state contract pharmacy statute substantially similar to S.B. 1414. *See PhRMA v. McClain*, 95 F.4th at 1143. This Court should follow the Eighth Circuit's reasoning and reject AbbVie's field preemption theory here.

b. S.B. 1414 does not conflict with the 340B statute.

The Court also should follow the Eighth Circuit in rejecting AbbVie's conflict preemption theories. *See PhRMA v. McClain*, 95 F.4th at 1144–45. A proper conflict preemption analysis requires parties to demonstrate that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This is a "high threshold," *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 607 (2011), and AbbVie comes nowhere close to meeting it.

The 340B statute was passed to help covered healthcare providers "reach[] more eligible patients and provid[e] more comprehensive services." HRSA, Final Rule, 340B Drug Pricing Program; ADR Regulation, 89 Fed. Reg. 28,643, 28,643 (Apr. 19, 2024) (hereinafter, "ADR Rule"). S.B. 1414, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer expanded healthcare to their patients. *See* Opp. at 24–25 (discussing the General Assembly's purpose in enacting S.B. 1414). Thus, not only does S.B. 1414 not stand as an obstacle to the purposes of the 340B statute, "rather it does the opposite: [S.B. 1414] assists in fulfilling the purpose of 340B." *PhRMA v. McClain*, 95 F.4th at 1144–45; *see also CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 83 (1987) (rejecting conflict preemption

challenge because, although state statute imposed additional rules in an area heavily regulated by a federal statute, it "further[ed] the federal policy" embodied by the federal statute).

AbbVie proffers three ways in which S.B. 1414 supposedly conflicts with the federal 340B statute, but each of AbbVie's arguments fails.

i. S.B. 1414 does not expand or redefine 340B covered entities.

The crux of AbbVie's attack on S.B. 1414 is a contention, repeated throughout AbbVie's brief, that S.B. 1414 expands the list of entities to which manufacturers are required to sell drugs at discounted prices, thus effectively "redefining '340B entity'" for purposes of the federal 340B statute to include contract pharmacies. Mot. at 12; *see also, e.g.*, *id.* at 1 ("Tennessee's law forces drug manufacturers to transfer their drugs at discounted prices to entities not contemplated by the federal 340B program.").

But S.B. 1414 *does not* redefine or expand which entities qualify for discounted pricing under the 340B program. To the contrary, the relevant provision of S.B. 1414 addresses only the delivery of 340B drugs *to 340B entities*; it provides that a drug company may not limit a 340B drug's acquisition by, or delivery to, "*a 340B entity*" or someone else "authorized by[] a 340B entity to receive 340B drugs *on behalf of the 340B entity*." S.B. 1414 § 1(c) (emphasis added). Every recipient of 340B drugs addressed by S.B. 1414 is either "a covered entity" or someone else "authorized by a 340B entity to receive 340B drugs on behalf of the 340B entity." *Id.* S.B. 1414 thus bars drug companies from discriminating between delivery locations for Tennessee 340B hospitals. And to borrow from the Eighth Circuit's description of a substantially similar Arkansas statute, "[S.B. 1414] does not require manufacturers to provide 340B pricing discounts to contract pharmacies" and "does not set or enforce discount pricing." *PhRMA v. McClain*, 95 F.4th at 1145; *see also PhRMA v. Murrill*, 2024 WL 4361597, at *9 ("[D]iscounts are set by the federal

government, not the State of Louisiana or Act 358. Act 358 addresses only contract pharmacies, a matter that is not addressed in Section 340B.").

ii. S.B. 1414 does not impede the federal ADR process.

AbbVie also urges that S.B. 1414's prohibitions on demanding certain types of information and disclosures from 340B hospitals, including claims and utilization data, *see* S.B. 1414 § 1(a)(1), impede manufacturers from pursuing the 340B program's ADR process for disputes between manufacturers and 340B hospitals. *See* Mot. at 13–15. AbbVie argues that S.B. 1414's data-collection provisions will prevent it from meeting the "reasonable cause" standard necessary to audit a 340B entity, which it is required to do before pursuing the federal ADR process. *See id.*

Not so. HRSA's guidance and practice confirm that the threshold that a drug manufacturer must meet before auditing a 340B entity is modest and does not require the sort of data addressed by S.B. 1414. Just last year, HRSA stated that the standards for initiating a manufacturer audit "are *not overly burdensome* or present *any barriers* to a manufacturer's ability to perform an audit of a covered entity." ADR Rule, 89 Fed. Reg. at 28,646 (emphasis added). As evidence, HRSA noted that "[i]n the last 5 years," it "has not denied a request for a manufacturer audit of a covered entity." *Id.* The standard itself, "reasonable cause," is defined broadly to mean "that a reasonable person *could* believe that a covered entity *may have* violated [certain provisions of the 340B statute]." HRSA, Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg, 65,406, 65,409 (Dec. 12, 1996). Manufacturers can meet this standard in various ways that require little evidence (and certainly do not require claims data)—for example, by pointing to "[s]ignificant changes in quantities of specific drugs ordered by a covered entity," or by citing "complaints from patients/other manufacturers about activities of a covered entity[.]" *Id.* at 65,406. *Amici* are not aware of a single instance when HRSA has *ever* required, as a condition of authorizing a manufacturer audit, the sort of data that AbbVie now claims it must be allowed to collect. Nor has

HRSA ever expected that a manufacturer would have access to such data until *after* it conducted an audit. *See* ADR Rule, 89 Fed. Reg. at 28,652 (noting that "manufacturers have the ability to gather needed information" for purposes of ADR "*through the audits*" (emphasis added)).

S.B. 1414's data-collection provisions do not impede manufacturers from conducting audits of covered entities and pursuing the ADR process.[8]

iii. S.B. 1414 does not create a "parallel enforcement regime."

Finally, AbbVie contends that the penalties and enforcement mechanisms in S.B. 1414 "contravene[] HRSA's exclusive enforcement authority by installing its own parallel enforcement regime." Mot. at 15; *see also id.* at 15–17. But S.B. 1414 does not authorize General Skrmetti or private citizens of Tennessee to "enforce[] *340B's requirements* through civil litigation," as AbbVie contends. Mot. at 17 (emphasis added). S.B. 1414 provides for the enforcement of *its own* requirements—not the requirements of the 340B statute. *See* S.B. 1414 § 1(d) (setting civil penalties for violations of specific subsections of S.B. 1414).

As the Eighth Circuit explained with respect to a similar Arkansas statute:

> Act 1103 ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies. Ark. Code Ann. § 23-92-604(c). The 340B Program, on the other hand, addresses discount pricing. Therefore, HHS has jurisdiction over different disputes: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs.

[8] Nor is there any merit to AbbVie's argument concerning S.B. 1414's prohibition on "[i]mpos[ing] any [340B-specific] requirement relating to the frequency, duration or scope of audits." Mot. at 14 (quoting S.B. 1414 § 1(a)(4)). This provision plainly does not, as AbbVie wrongly suggests, "prohibit[] manufacturers from pursuing the very federally authorized audits they *must* undertake as a prerequisite to accessing the federal ADR system." *Id.* (citing 42 U.S.C. § 256b(d)(3)(A)). Rather, the challenged provision speaks of manufacturers "*impos[ing] any requirements*" of their own relating to 340B-specific audits, S.B. 1414 § 1(a)(4) (emphasis added)—for example, through a right-to-audit contract clause.

PhRMA v. McClain, 95 F.4th at 1144. Because the requirements that can be enforced under S.B. 1414 (like the statute in *PhRMA v. McClain*) are different from the 340B program requirements, it does not pose any obstacle to the 340B program's enforcement regime.

B. S.B. 1414 Does Not Violate the Takings Clause.

AbbVie's Takings Clause claim likewise fails. Courts have uniformly rejected AbbVie's and other drug companies' Takings Clause challenges to similar prohibitions on refusing to deliver 340B drugs to contract pharmacies. *See AstraZeneca v. Bailey*, 2025 WL 644285, at *4; *PhRMA v. Murrill*, 2024 WL 4361597, at *13–15; *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20; *Eli Lilly & Co. v. HHS*, 1:21-cv-81-SEB-MJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021). In particular, *amici* respectfully refer the Court to the Southern District of Mississippi's decision in *AbbVie v. Fitch* for a compelling, point-by-point rejection of the exact same Takings Clause arguments that AbbVie now polishes off and repurposes for this case. *See* 2024 WL 3503965, at *16–20. This Court should join the growing chorus of resounding rejections of Takings Clause challenges to 340B contract pharmacy statutes.

First, AbbVie is simply wrong in arguing that S.B. 1414 "forces drug manufacturers to transfer their drugs at discounted prices to entities not contemplated by the federal 340B program." Mot. at 1; *see also id.* at 19 ("If not enjoined, Tennessee's law would force AbbVie to transfer its property against its will to third parties."). Any drug company that chooses to participate in the 340B program must offer its drugs at or below a statutory ceiling price to 340B entities. *See* 42 U.S.C. § 256b(a). S.B. 1414 does not address sales to any party other than a 340B entity; it simply prohibits drug companies from interfering with a 340B drug's acquisition by, or delivery to, "a 340B entity" or an entity "authorized by[] a 340B entity to receive 340B drugs *on behalf of* the 340B entity." S.B. 1414 § 1(c) (emphasis added). S.B. 1414 thus addresses only sales *to 340B*

entities—the very sales that are already contemplated under the federal 340B statute. S.B. 1414 does *not* address (let alone require) sales "to entities not contemplated by the federal 340B program." Mot. at 1; *see AbbVie v. Fitch*, 2024 WL 3503965, at *19 ("Nor is the Court persuaded that the manner of delivery to covered-entity patients can constitute a *per se* taking: Plaintiffs are still only required to sell at 340B discounts *to covered entities*." (emphasis added)).

Second, even if S.B. 1414 could somehow be read to extend the 340B ceiling price to AbbVie's sales to *additional* buyers that are "not contemplated by the federal 340B program," Mot. at 1, AbbVie still comes nowhere near showing a violation of the Takings Clause. Indeed, AbbVie barely argues that its property is being "taken" at all. All AbbVie says is that "[t]elling manufacturers that they *cannot* include certain conditions on the sale of their drugs and *cannot* interfere with the acquisition of their drugs by contract pharmacies is the same as *forcing* manufacturers to sell their drugs at confiscatory prices under conditions favored by the state." Mot. at 18–19 (emphasis in original). But regulating the conditions under which AbbVie may sell its drugs (which are *personal* property) cannot amount to a compensable taking, even if the regulation deprived AbbVie's drugs of all sale value—which AbbVie does not (and could not) argue:

> [I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [a property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless (at least if the property's only economically productive use is sale or manufacture for sale).").

See Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1027–28 (1992). That principle is fatal to AbbVie's Takings claim.[9]

[9] AbbVie does not argue that price-capped sales of 340B drugs entail a physical invasion of its property, nor could it. *See Yee v. City of Escondido, Cal.*, 503 U.S. 519, 532 (1992) (holding that rent-control ordinance did not amount to a physical taking); *see also Tenn. Scrap Recyclers Ass'n v. Bredesen*, 556 F.3d 442, 453 (6th Cir. 2009) ("Regulations of a party's use of its property are not physical takings.").

Third, AbbVie gets nowhere by contending that the sale of 340B drugs under the conditions set forth in S.B. 1414 "is not a 'public use' recognized in American law." Mot. at 19 (citation omitted). AbbVie's argument concerning "public use" is beside the point given the lack of any "taking" at all. It is also wrong: state contract pharmacy statutes like S.B. 1414 "assist[] in fulfilling the purpose of [the 340B program]," which Congress created "to support" covered entities that "perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *PhRMA v. McClain*, 95 F.4th at 1141, 1145. That is plainly a "public purpose" that fits comfortably within the "broad and inclusive" parameters that the Supreme Court has repeatedly reaffirmed under the Takings Clause. *Kelo v. City of New London*, 545 U.S. 469, 480–81 (2005) (citation omitted).

Fourth, and perhaps most fundamentally, AbbVie cannot construe S.B. 1414 (or the 340B program itself) as compelling transfers of its property to private parties because AbbVie participates in the 340B program *voluntarily*. AbbVie expressly concedes this incontrovertible fact, which dooms its Takings Clause claim. *See* Compl. ¶ 5 (acknowledging that participation in the 340B program is "a voluntary choice"). In the healthcare context, courts routinely reject Takings Clause claims where the plaintiff voluntarily participates in the program that it claims is taking its property.[10] Because participation in the 340B program is voluntary, AbbVie is not being "force[d] . . . to transfer its property against its will to third parties and under conditions it would

[10] *See Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014), *cert. denied*, 575 U.S. 1008 (2015); *Minn. Ass'n of Health Care Facilities v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993); *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 968–73 (11th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983); *Eli Lilly & Co. v. HHS*, 2021 WL 5039566, at *21; *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 207–10 (D.N.J. 2021), *rev'd on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20.

never have agreed to," Mot. at 19, and its Takings Clause claim must fail. *See AbbVie v. Fitch*, 2024 WL 3503965, at *17–19 (addressing voluntariness).

AbbVie's attempt to sidestep the voluntary participation doctrine is unavailing. *See* Mot. at 19–20. According to AbbVie, it "voluntarily accepted *federal* 340B obligations as a condition of participating in the *federal* Medicare and Medicaid programs," but not *state*-imposed obligations like the ones set forth in S.B. 1414. Mot. at 19. Even before S.B. 1414 and similar statutes in other states were enacted, such contract pharmacy requirements "should have been foreseeable to [AbbVie], as Section 340B has had a well-known 'gap' about how delivery must occur," *AbbVie v. Fitch*, 2024 WL 3503965, at *19–20. Drug companies not only argued in favor of that gap, but in light of 340B hospitals' longstanding use of contract pharmacies, "[AbbVie] could have foreseen that states might enact policies favoring dispensation at contract pharmacies." *id.*; *accord PhRMA v. Murrill*, 2024 WL 4361597, at *15 (rejecting Takings claim because "regulations requiring delivery and forbidding restrictions against delivery to contract pharmacies were foreseeable"); *see also Nat'l Lifeline Assoc. v. FCC*, 983 F.3d 498, 515 (D.C. Cir. 2020) ("[W]hen an owner of property voluntarily participates in a regulated market, additional regulations that may reduce the value of the property regulated do not result in a taking." (citation omitted)). Tellingly, even though AbbVie is now apprised of S.B. 1414 and similar statutes in other states, it continues to voluntarily participate in the 340B program.[11]

[11] AbbVie offers no support for the supposed principle that its voluntary participation in the federal 340B program "cannot justify separate state-imposed requirements where no state benefit is conferred." Mot. at 19. AbbVie relies on a D.C. Circuit case, *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023), that did not involve any state law and that the D.C. Circuit itself said was "tied to the particular circumstances" of that case, *id.* at 1239; *see Bristol Myers Squibb Co. v. Becerra*, No. 23-3335, 2024 WL 1855054, at *8 (D.N.J. Apr. 29, 2024) (rejecting drug company reliance on *Valancourt Books*). Here, the "particular circumstances" differ immensely because, unlike the property owner in *Valancourt Books*, AbbVie is not required under

C. S.B. 1414 Does Not Violate the First Amendment.

AbbVie has no credible argument that S.B. 1414 violates its First Amendment right to petition the government for a redress of grievances.[12] AbbVie's First Amendment theory is that S.B. 1414 "effectively bar[s] [it] from accessing the federal ADR system" by preventing it from demanding certain types of information from 340B entities. Mot. at 23. AbbVie's entire argument is that S.B. 1414's information-gathering restrictions prevent it from making "good faith efforts" to resolve disputes with 340B entities, which it is required to do before initiating the ADR process. 42 C.F.R. § 10.21(b)(4); *see* Mot. at 23.[13] General Skrmetti convincingly explains why AbbVie's theory is "not cognizable under the Petition Clause." Opp. at 21.

S.B. 1414 to *entirely* surrender its property with no economic value in return: AbbVie receives payment from hospitals for the drugs it sells to them—including when the drugs are delivered to contract pharmacies.

Even if AbbVie's requirement of an additional state-law benefit had some basis in precedent—and it does not—AbbVie plainly receives an important benefit from Tennessee in exchange for compliance with Tennessee law. AbbVie seems to forget that Medicaid is a "cooperative federal-state program." *John B. v. Emkes*, 710 F.3d 394, 398 (6th Cir. 2013). And state Medicaid coverage of outpatient drugs is largely optional, not mandatory. *See* 42 U.S.C. § 1396a(54); *see also PhRMA v. Walsh*, 538 U.S. 644, 665 (2003) ("We have made it clear that the Medicaid Act gives the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in the best interest of the recipients." (citation omitted)). Tennessee's decision to cover such drugs confers a specific benefit on AbbVie and other drug manufacturers. Tennessee could revisit that decision, along with others that benefit AbbVie and other drug manufacturers, if they refuse to comply with its laws concerning delivery of 340B drugs. This is more than enough to meet the "additional-state-benefit" standard that AbbVie has invented out of whole cloth.

[12] Although in its Complaint AbbVie invokes both the Free Speech and Petition Clauses of the First Amendment, *see* Compl. ¶¶ 208–17, AbbVie addresses only the Petition Clause in its Motion for a Preliminary Injunction. *See* Mot. at 23–24.

[13] AbbVie mischaracterizes the ADR guidelines as requiring a "good faith inquiry," Mot. at 23, when in fact they require "good faith efforts" to resolve the dispute. 42 C.F.R. § 10.21(b)(4); *see also* HRSA, Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. at 65412 ("Prior to the filing of a request for dispute review with the Department, the parties must *attempt, in good faith, to resolve the dispute*." (emphasis added)). Elsewhere in its brief, AbbVie describes the good-faith requirement correctly. *See* Mot. at 14.

But even assuming for the sake of argument that the Petition Clause could be implicated in this context, AbbVie's claim fails for the obvious reason that it can *ask* 340B entities for any needed information about disputed drug claims without offending S.B. 1414. S.B. 1414 prohibits a manufacturer only from "*[r]equir[ing]* a 340B entity . . . to clarify a claim" (unless doing so is "in the normal course of business and not related to the 340B program"). S.B. 1414 § 1(a)(2) (emphasis added); *see also id.* § 1(a)(1), 1(a)(3)–(6) (forbidding manufacturers from imposing "requirements" on 340B entities). Contrary to AbbVie's misrepresentation, there is no prohibition on "*asking* a '340B entity' to 'clarify a claim'" Mot. at 23 (emphasis added, citation omitted).

AbbVie cannot credibly argue that asking a 340B entity for any needed information is not enough to satisfy HRSA's "good faith" conferral requirement. Indeed, HRSA regulations say that it is sufficient if the party initiating ADR "has made *attempts to contact* the opposing party regarding the specific issues cited in the ADR claim." 42 C.F.R. § 10.21(b)(4) (emphasis added).

AbbVie has no coherent theory as to how S.B. 1414 impedes its access to the ADR process, and it is therefore not likely to succeed in establishing a violation of the Petition Clause.

II. AN INJUNCTION WOULD NOT SERVE THE PUBLIC INTEREST.

The public interest would not be served by enjoining S.B. 1414 and allowing manufacturers to interfere with Tennessee 340B hospitals' partnerships with contract pharmacies. Contract pharmacy arrangements play a crucial role in 340B hospitals' ability to serve their communities.

AbbVie spends a significant portion of its Complaint maligning hospitals that rely on the 340B program and that partner with contract pharmacies. *See* Compl., ECF No. 1, ¶¶ 42–80. But this is not how the Supreme Court has viewed 340B hospitals. As Justice Kavanaugh wrote for a unanimous Supreme Court just a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022).

Savings from the 340B program are crucial in enabling 340B hospitals to continue serving these communities. For example, East Tennessee Children's Hospital in Knoxville, Tennessee has used savings from the 340B program to help support numerous programs and services, including a residency program for new doctors and a program that provides inhalers to children who cannot afford them. Ascension Saint Thomas—a health system with 340B locations in Centerville, Murfreesboro, McMinnville, and Waverly, Tennessee—uses 340B savings to support its charitable clinics as well as a program that provides free and reduced-cost medications to uninsured patients, among other programs and services. Some of Ascension Saint Thomas's 340B locations have negative operating margins, including Ascension Saint Thomas Hickman—a critical access hospital in Hickman County that serves roughly 10,000 patients each year, with the nearest other hospital being 30 miles away. Savings from the 340B program help Ascension Saint Thomas to stretch its scarce resources, provide uncompensated care, and serve its community.[14]

Relationships with contract pharmacies play a crucial role in 340B hospitals' ability to serve their communities. Partnerships with contract pharmacies "allow for drug dispensation closer to where low-income patients reside." *PhRMA v. McClain*, 95 F.4th at 1139. As HRSA has noted in issuing guidance for 340B hospitals' use of contract pharmacies:

> It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities. This would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies, and patients served.

HRSA, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

[14] *See* Ascension, *Tennessee Covered Entities*, https://about.ascension.org/about-us/community-impact/340b-drug-pricing-program/tennessee.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[15] "This is in large part due to the fact that building or maintaining a pharmacy is cost-prohibitive for many covered entities." *PhRMA*, 95 F.4th at 1139. Even fewer—only one in five 340B hospitals—have in-house "specialty" pharmacies, which many insurers require for the dispensing of "specialty" drugs. These drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than non-specialty drugs.[16] Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy outside of its in-house pharmacy.[17] Some 340B hospitals—including East Tennessee Children's Hospital—have had to terminate relationships with contract pharmacies that previously served many of their patients in large part because of restrictions imposed by drug manufacturers.

Moreover, a quarter of hospitals' 340B benefit historically came from drugs dispensed at contract pharmacies. The drug industry's efforts to stop 340B hospitals from relying on contract pharmacies has hurt 340B hospitals and adversely impacted their ability to serve at-risk populations. Denied 340B savings associated with contract pharmacies, many 340B hospitals—which typically operate with razor-thin (and often negative) margins—report that they have been forced to curtail critical programs and services or eliminate them entirely.[18]

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[15] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* 2, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[16] Adam J. Fein, Drug Channels Institute, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?* (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html.

[17] 340B Health, *supra* note 15, at 7 (citing Adam J. Fein, Drug Channels Institute, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2022)).

[18] 340B Health, *Restrictions on 340B Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* at 2, 5, 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

The General Assembly, with an unbiased interest in protecting Tennessee citizens, hospitals, and pharmacies, has acted to advance the objectives of the 340B program and protect 340B hospitals' ability to serve their communities by partnering with contract pharmacies. Enjoining S.B. 1414 would not serve the public interest.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction should be denied.

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Respectfully submitted,

s/ Simon N. Levitsky
William T. Ramsey (#009245)
James G. Thomas (#007028)
Nathan C. Sanders (#033520)
Simon N. Levitsky (#040944)
NEAL & HARWELL, PLC
1201 Demonbreun St., STE 1000
Nashville, TN 37203
(T) (615) 238-3503
(F) (615) 726-0573
wtr@nealharwell.com
jthomas@nealharwell.com
nsanders@nealharwell.com
slevitsky@nealharwell.com

William B. Schultz*
Margaret M. Dotzel*
Ezra B. Marcus*
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
(T) (202) 778-1800
(F) (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
emarcus@zuckerman.com

Counsel for Amici Curiae

** pro hac vice motion forthcoming*